

OCT 20 1999

Dr. Henry Yang
Rhone-Poulenc Ag Company
P. O. Box 12014
2 T. W. Alexander Drive
Research Triangle Park, NC 27709-2014

Dear Dr. Yang:

This is in regard to Rhone-Poulenc's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on its genetically modified Navigator canola line, Oxy-235. According to Rhone-Poulenc, this new line is modified to express the *oxy* (also known BXN[®]) gene isolated from *Klebsiella pneumoniae* subsp. *ozaenae*. The *oxy* gene encodes the nitrilase enzyme, which confers resistance to bromoxynil, the active ingredient in the herbicide Buctril[®].

As part of bringing the consultation regarding this product to closure, Rhone-Poulenc submitted a summary of its safety and nutritional assessment of the genetically modified Navigator canola on May 10, 1999. These communications informed the FDA of the steps taken by Rhone-Poulenc to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Rhone-Poulenc has conducted, it is our understanding that Rhone-Poulenc has concluded that canola seeds, meal and oil derived from the new variety are not materially different in composition, safety, and other relevant parameters from other canola seeds, meal, and oil currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0064. This file will be maintained in the Office of Premarket Approval.

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Based on the information Rhone-Poulenc has presented to FDA, we have no further question concerning seeds, meal, and oil from canola line Oxy-235 at this time. However, as you are aware, it is Rhone-Poulenc's continued responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely

/s/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
And Applied Nutrition

cc: HFS-200 HFS-205 HFS-206 HFS-207 HFS-226 HFS-235
 HFS-246 HFS-247 HFS-13 HFV-200 HFV-221 HFV-228
 BNF0064